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APPLICATION NO. 10/151,151	FILING DATE 11/17/00	TO FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM22/0508

EXAMINER  
JARVIS, W

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/08/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/666,068</b>	Applicant(s) <b>Tobinick</b>
	Examiner <b>William R. A. Jarvis</b>	Art Unit <b>1614</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 50-65 and 100 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 50-65 and 100 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1
- 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other: \_\_\_\_\_

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 50-65 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaines et al, Szalay et al, Person, or Seekamp et al. Gaines teaches that the inhibition of TNF with a soluble TNF receptor I construct was effective at attenuating skeletal muscle damage caused by ischemia/reperfusion injury. Szalay teaches that TNF inhibits myogenesis by inhibiting the expression of myogenic transcription factors; one skilled in the art would reasonably conclude that inhibition of TNF would attenuate this inhibition of myogenesis. Person teaches that the TNF antagonist pentoxifylline is effective at treating applicant's preferred muscular disorder dermatomyositis. Seekamp teaches that polyclonal antibodies to TNF-alpha as well as soluble TNF receptors were effective at protecting against vascular injury in muscle. Applicant's claims differ in that they require TNF antagonists not specifically mentioned by the prior art. However, since the prior art teaches that several types of TNF antagonists are effective at treating muscular disorders and, one skilled in the art would have been motivated to treat muscular disorders with any type of TNF antagonist. To treat muscular dystrophy with TNF antagonists is obvious since Szalay teaches that TNF inhibits expression of myogenic transcription factors which is closely related to the etiology of muscular dystrophy. The claimed amounts and modes of administration are obvious since it is within the skill of the artisan to determine the modes of administration and

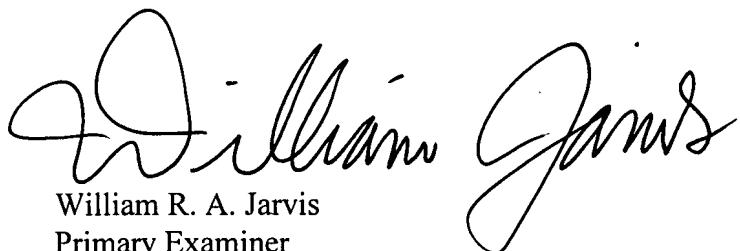
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amount of drug that provides the therapeutic effect required by the patient while minimizing adverse side effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. A. Jarvis whose telephone number is (703) 308-4613. My normal office hours are Monday, Tuesday, Thursday, and Friday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "William Jarvis".

William R. A. Jarvis  
Primary Examiner  
Art Unit 1614  
May 5, 2001